UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,517	10/31/2003	Dale B. Schenk	015270-008920US	8113

20350 7590 06/06/2007

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
STANDLEY, STEVEN H	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
06/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,517	SCHENK ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/22/017*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-46,48,50-55,71-76 and 78-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-46,48,50-55,71-76 and 78-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

The amendment filed 1/22/07 has been made of record. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Finality of this application is withdrawn, and prosecution is reopened. Claims 41-46, 48, 50-55, 71-76, and 78-84 are under examination.

Objections/Rejections: Withdrawn

Rejection of claims 41-46, 49, and 50-55 under 35 USC § 112, 1st enablement, as it relates to a method of 'curing' is withdrawn. However, the methods as they relate to prophylactic treatment are still rejected (see arguments below).

Objections/Rejections: Maintained/New Grounds

Claim Rejections - 35 USC § 112

Rejection of claims 41-46, 48, and 50-55 and 71-76, and 78-80 under 35 USC § 112, 1st paragraph, enablement is maintained for the reasons made of record in the office action dated 10/07/05 and 5/15/06. Claims 41-46, 48, and 50-55 are still rejected to the extent that 'therapeutically treating' includes prophylactically treating. Applicant's arguments have been fully considered and not found to be persuasive. The definition of therapeutically treating that applicant has provided in the specification (page 45, [0137]) includes administration to patients ***suspected of***, or already suffering from the disease and to ***prophylactically treating***. Moreover, 'prophyllaxis,' as recited in the definition

the examiner has provided (page 6 of the action of 10/07/05), and to which Applicant finds no disagreement, is treating a patient without the disease, because prophylaxis is, 'prevention of a disease or process that can lead to disease.' Therefore the patient treated initially does not have the disease. Furthermore, the dependent claim 48 recites, 'wherein the patient has a risk factor for the disease.' Thus, the Applicant is clearly indicating that independent claim 41 (to which claim 48 depends) includes a method of administering to a patient with no signs or symptoms or risk factors of the disease. Furthermore, claims 71-76 and 78-80 are directed ***exclusively at prophylactically treating***. ~~Prior arguments made~~ ??.

Because the Examiner interprets the treatable patient population in claims 41-46, 48, and 50-55 to include patients free of the disease, disease signs, or symptoms, and because claims 71-76 and 78-80 exclusively relate to prophylactically treating, the claims remain rejected as not enabled for reasons made of record in the actions of 4/07/05, 9/30/05, 10/07/05, 5/15/06, and for the reasons argued below.

Applicant argues on page 7 of the Appeal Brief that ""enabling the full scope of a claim does not necessarily require enabling every embodiment." This is not found persuasive for two reasons: Because the non-enabled embodiment of prophylactically treating expands the scope of the method of treating such that the ***majority of the patients treated*** (i.e., persons with no signs, symptoms or risks for PD) are contained within the non-enabled embodiments of claims 41-46, and because claims 71-76 and 78-80 are directed exclusively at prophylaxis, which is not enabled for the reasons mad of record and the reasons argued herein.

The nature of the invention is a complex method of prophylactically treating, which is prevention of the disease or a process that can lead to the disease. It is complex because: 1) it is presently impossible to predict PD in the general population, therefore the treatment prevents PD in patients who will never get the disease, 2) PD has a wide-range of age of onset from as early as the 30s to as late as the 90s so it is impossible to know when prophylactic treatment should begin. 3) PD may be caused by, or influenced by, ***a multitude of factors*** including toxins (see below) which means the treatment must work to prevent multiple and unrelated mechanisms leading to the disease.

The prior art establishes several factors that indicate the invention does not work. Firstly, the animal model used to enable the treatment of PD herein does not include animals 'at risk for' the disease because all animals get it, or animals in which the process that leads to PD is absent (so that 'prophylaxis' can be tested). In other words, prophylaxis cannot be tested because all animals in the animal model are destined to get the disease. The transgenic animals used all develop symptoms of PD such Lewy body deposits and neuropathology and therefore do not enable treatment of a patient 'at risk for PD.' Secondly, immunization of animals that are not predisposed to PD results in substantial brain damage, thereby occluding any therapeutic value. Thirdly, the art is silent as to predicting non-familial PD. Thus PD cannot be diagnosed in the general population before the onset of any symptoms.

The genetically altered mice used to enable the invention herein ALL have measurable symptoms and neuropathology associated with ***mutant*** human synuclein

deposition. See Lee et al. (2002), figures 2-5, in which it is demonstrated that all transgenic animals show various measurements of synuclein deposition and neuropathology. Thus, there are no animals reasonably representing a population 'at risk' of getting PD. They all get symptoms of PD. Furthermore, much evidence suggests that environmental factors such as toxins play a key role in initiating PD (Di Monte et al, 2002). The number of environmental factors having been associated with PD is fairly staggering. Skipper et al (2002) list rural living, well water, premorbid personality disorder and smoking, for instance. Furthermore, Skipper et al conclude that there is little, if any, genetic influence on idiopathic (i.e., non-familial) PD (page 503). Considering that familial Parkinson's is ***rare*** and idiopathic Parkinson's is ***common***, the animal model (which is based on genetic PD) does not model ANY aspect of the onset or etiology of the great majority of Parkinson's disease. The animal model does not take into account ***any other effects but the ones caused by the transgenic animal expressing mutant human synuclein***. Therefore it cannot treat a patient 'at risk' for PD.

The prior art indicates immunization with A-beta compromises the blood-brain barrier, activates cns glia, and induces peripheral hemorrhage (see Su et al, 1999). Furthermore, the prior art indicates treatment of AD patients with A-beta results in meningoencephelitis (Schenk, 2002). Therefore, immunizing a population not at risk, or at risk of AD or PD with A-beta can induce an inflammatory response that is detrimental to the health and cognitive function of the patient (which the disease is attempting to treat). Furthemore, the molecular precursor to A-beta, APP, is well-known to have

important physiological functions. Therefore raising an immune response to a molecule with important physiological functions could harm the asymptomatic patient (Hooper et al, 2000).

The specification lacks any enabling disclosure by way of instruction or example of prophylactic treatment. There are no animals treated that are 'at risk of' getting PD.

Therefore given the complexity of the invention, the contrasting prior art, and the lack of any teaching or example in the specification, it would require undue experimentation for one of skill in the art would to know how to use the invention as claimed.

Claim Rejections - 35 USC § 102

Rejection of claims 41, 42, 44, 45, 46, 48, 50, 51-55, 71, 72 74, 75 and 76, and 80-84 under 35 USC § 102(e) over Jensen is maintained for the reasons made of record in the office action dated 10/07/05. Applicant's arguments have been fully considered and not found to be persuasive. See the Examiner's arguments in the previous office actions of 10/07/05 and 5/15/06.

Claim Rejections - 35 USC § 103

Rejection of claims 41, 43-46, 48, 50-55, 71, 73-76, 78-80 and 80-84 under 35 USC § 103(a) is maintained for the reasons made of record in the office action dated 10/07/06. Applicant's arguments have been fully considered and not found to be persuasive. Applicant's arguments have been fully considered and not found to be

persuasive. See the Examiner's arguments in the previous office actions of 10/07/05 and 5/15/06.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
5/28/07

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER